DETAILED ACTION

1. Applicant's amendment and response filed 12/22/10 is acknowledged and has been entered.

2. Applicant is reminded of Applicant's election of Group I, and species of peptide consisting of the amino acid sequence of amino acid residues 80-109 of SEQ ID NO: 1 in Applicant's amendment and response filed 9/9/10 is acknowledged.

Claims 1-8 read on the elected species and are presently being examined.

Appropriate correction is required.

3. Applicant's amendment filed 12/22/10 has overcome the prior rejection of record of claims 1-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

4. Applicant's amendment filed 12/22/10 has overcome the prior objection of record of claim 1.

5. The amendment filed 12/22/10 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The sequence listed as SEQ ID NO: 1 in the sequence listing of the instant application (as amended in the amendment filed 12/22/10) does not match the sequence of SEQ ID NO: 1 in U.S. Patent No. 5,804,381 and Chen *et al* (PNAS USA 94: 1914-1918, 1997), the disclosures of which are incorporated by reference (see the paragraph spanning pages 2-3 of the instant specification and lines 10-15 on page 4). The sequences disclosed/taught in U.S. Patent No. 5,804,381 and Chen *et al* (PNAS USA 94: 1914-1918, 1997 have glycine at position 44 which differs from position 44 of SEQ ID NO: 1 in the instant sequence listing (*i.e.,* alanine).

Note that in the provisional parent application 60/474,893 the sequence of NY-ESO in said provisional application and in the sequence listing for said provisional application lists "Aly" at position 44.

Applicant is required to cancel the new matter in the reply to this Office Action.

6. For the purpose of prior art rejections, the filing date of the instant claims is deemed to be the filing date of the instant application*, i.e.,* 2/11/08, as the parent applications do not support the claimed limitations of the instant application. The said parent applications do not provide support for SEQ ID NO: 1 (as amended in the amendment

filed 12/22/10) as enunciated supra. In addition, said the provisional parent application does not provide support for at least one additional peptide that consists of an amino acid sequence "derived from" NY-ESO-1.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by WO2004029274 A2.

This is a new ground of rejection necessitated by Applicant's amendment filed 12/22/10.

WO2004029274 A2 teaches the peptide ARGPESRLLEFYLAMPFATPMEAELARRSL (amino acid residues 80-109 of SEQ ID NO: 1 of instant claim 1 and SEQ ID NO: 4 of the art reference) and a pharmaceutical composition thereof, and which composition may further comprise at least one additional peptide such as SEQ ID NO: 5 of the art reference which is also from NY-ESO-1 and that contains both class I and class II binding peptides (HLA-A2 and HLA-DP4, respectively) or at least one additional peptide such as amino acid residues 13-21 or 15-23 of SEQ ID NO: 5 or amino acid residues 1-9 of SEQ ID NO: 4, all of which bind to a MHC class I molecule), and adjuvant(s) or immunostimulatory molecules (see entire reference, especially claims 1-5, 10 and 16, [005], [0040], [0042], [0081]-[0083]).

9. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by US20030175250 A1.

This is a new ground of rejection necessitated by Applicant's amendment filed 12/22/10.

US20030175250 A1 discloses an isolated peptide consisting of the sequence ARGPESRLLEFYLAMPFATPMEAELARRSL (amino acid residues 80-109 of SEQ ID NO: 1 of instant claim 1 and SEQ ID NO: 16 of the art reference), and composition thereof further comprising IL-2, an adjuvant. US20030175250 A1 further discloses that the said peptide is from NY-ESO-1 and is processed by antigen presenting cells (APCs) into multiple epitopes with various HLA restriction. US2003075250 A1 discloses that the

peptide is immunogenic (especially Example 9). US20030175250 A1 also discloses compositions comprising immunogenic peptides in a pharmaceutically acceptable carrier which may be an adjuvant and *in vivo* administration of said compositions in order to alleviate a disorder characterized by expression of an NY-ESO-1 peptide (especially claims, [0067]).

10. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by US20030175250 A1.

This is a new ground of rejection necessitated by Applicant's amendment filed 12/22/10.

US20030175250 A1 discloses an isolated peptide consisting of the sequence ARGPESRLLEFYLAMPFATPMEAELARRSL (amino acid residues 80-109 of SEQ ID NO: 1 of instant claim 1 and SEQ ID NO: 16 of the art reference), and composition thereof further comprising IL-2, an adjuvant. US20030175250 A1 further discloses that the said peptide is from NY-ESO-1 and is processed by antigen presenting cells (APCs) into multiple epitopes with various HLA restriction. US2003075250 A1 discloses that the peptide is immunogenic (especially Example 9). US20030175250 A1 also discloses compositions comprising immunogenic peptides in a pharmaceutically acceptable carrier which may be an adjuvant and *in vivo* administration of said compositions in order to alleviate a disorder characterized by expression of an NY-ESO-1 peptide (especially claims, [0067]).

11. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by US 7,259235 B2.

This is a new ground of rejection necessitated by Applicant's amendment filed 12/22/10.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US 7,259235 B2 discloses a peptide ARGPESRLLEFYLAMPFATPMEAELARRSL (amino acid residues 80-109 of SEQ ID NO: 1 of instant claim 1 and SEQ ID NO: 4 of the art reference) and pharmaceutical composition thereof, and which composition may further comprise at least one additional peptide such as SEQ ID NO: 5 of the art reference which is also from NY-ESO-1 and that contains both class I and class II binding peptides (HLA-A2 and HLA-DP4, respectively) or at least one additional peptide such as amino acid residues 13-21 or 15-23 of SEQ ID NO: 5 or amino acid residues 1-9 of SEQ ID NO: 4, all of which bind to a MHC class I molecule), and adjuvant(s) or immunostimulatory molecules (see entire reference, especially claims, paragraph spanning columns 13-14 and examples).

12. Claims 1-8 are rejected under 35 U.S.C. 102(a) as being anticipated by US 7,259235 B2.

This is a new ground of rejection necessitated by Applicant's amendment filed 12/22/10.

US 7,259235 B2 discloses a peptide ARGPESRLLEFYLAMPFATPMEAELARRSL (amino acid residues 80-109 of SEQ ID NO: 1 of instant claim 1 and SEQ ID NO: 4 of the art reference) and pharmaceutical composition thereof, and which composition may further comprise at least one additional peptide such as SEQ ID NO: 5 of the art reference which is also from NY-ESO-1 and that contains both class I and class II binding peptides (HLA-A2 and HLA-DP4, respectively) or at least one additional peptide such as amino acid residues 13-21 or 15-23 of SEQ ID NO: 5 or amino acid residues 1-9 of SEQ ID NO: 4, all of which bind to a MHC class I molecule), and adjuvant(s) or immunostimulatory molecules (see entire reference, especially claims, paragraph spanning columns 13-14 and examples).

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being obvious over US 20030175250 A1 in view of Zeng *et al* (PNAS 2001 98(7): 3964-3969).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that

the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

This is a new ground of rejection necessitated by Applicant's amendment filed 12/22/10.

US20030175250 A1 discloses an isolated peptide consisting of the sequence ARGPESRLLEFYLAMPFATPMEAELARRSL (amino acid residues 80-109 of SEQ ID NO: 1 of instant claim 1 and SEQ ID NO: 16 of the art reference), and composition thereof further comprising IL-2, an adjuvant. US2003075250 A1 further discloses that the said peptide is from NY-ESO-1 and is processed by antigen presenting cells (APCs) into multiple epitopes with various HLA restriction. US20030175250 A1 discloses that the peptide is immunogenic (especially Example 9). US20030175250 A1 also discloses compositions comprising immunogenic peptides in a pharmaceutically acceptable carrier which may be an adjuvant and *in vivo* administration of said compositions in order to alleviate a disorder characterized by expression of an NY-ESO-1 peptide (especially claims, [0067]). US2003075250 A1 discloses that it is desirable to also stimulate an antibody response (for example, [0080]-[0081]).

US20030175250 A1 does not disclose wherein the composition further comprises at least one additional peptide as recited in instant claims 3-6.

Zeng *et al* teach that it is desirable to provide vaccines that generate both CD4+ (class II MHC binding peptides) and CD8+ (class I MHC binding peptides) T cell responses (see entire reference, especially abstract, introduction and discussion).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have formulated the art peptide disclosed by US20030175250 A1 (amino acid residues 80-109 of SEQ ID NO: 1 of instant claim 1 and SEQ ID NO: 16 of the art reference) in a pharmaceutically acceptable carrier, including an adjuvant, as is disclosed for other peptides in the said art reference.

One of ordinary skill in the art would have been motivated to do this in order to generate an immune response to multiple HLA types, particularly in light of the teaching of the art reference that the art peptide is processed by APCs into multiple epitopes having various HLA restriction.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have formulated the peptide disclosed by US20030175250 A1 with at least one other NY-ESO-1 peptide, including a peptide that binds to MHC class I (including from a different portion of NY-ESO-1 than the art peptide) and/or a peptide that binds to MHC class II.

One of ordinary skill in the art would have been motivated to do this in order to generate an immune response that encompasses both CD8+ and CD4+ T cell responses as taught by Zeng *et al*.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No.7,259,235 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 4 of '235 is amino acid residues 80-109 of SEQ ID NO: 1 of the instant claims, the other peptides recited in the claims of '235 are or contain class I MHC and/or class II MHC epitopes. In addition, a composition comprising the peptide(s) and a pharmaceutically acceptable carrier is an obvious variant, including wherein the carrier is an adjuvant. Alternatively, it would have been prima facie obvious to have formulated the composition of the claims of '235 with PBS, a pharmaceutically acceptable carrier, and/or an adjuvant, as the peptide(s) are subsequences from tumor antigen protein NY-ESO-1.
17. No claim is allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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